

Amendment No. 1 to HB0667

Terry
Signature of Sponsor

AMEND Senate Bill No. 675

House Bill No. 667*

by deleting all language after the enacting clause and substituting:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 5, is amended by deleting the part and substituting:

63-10-501. Short title.

This part is known and may be cited as the "Kevin Clauson Drug Donation Act."

63-10-502. Part definitions.

As used in this part:

- (1) "Anti-rejection drug" means a prescription drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ;
- (2) "Board" means the board of pharmacy;
- (3) "Cancer drug" means a prescription drug that is used to treat:
 - (A) Cancer or the side effects of cancer; or
 - (B) The side effects of a prescription drug that is used to treat cancer or the side effects of cancer;
- (4) "Controlled substance" has the same meaning as defined in § 39-17-402;
- (5) "Department" means the department of health;
- (6) "Donor" means any of the following with a license or permit in good standing in the state in which the person or entity is located and that donates prescription drugs to a repository program approved pursuant to this part:
 - (A) A person;

- (B) A pharmacy;
- (C) A medical facility;
- (D) A drug manufacturer or wholesaler licensed by the board; or
- (E) A prison or government entity federally authorized to possess prescription drugs;

(7) "Eligible individual" means an indigent, an uninsured person, or an underinsured person who meets the criteria for eligibility pursuant to this part;

(8) "Indigent" means a person with an income that is below six hundred percent (600%) of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services;

(9) "Medical facility" means:

- (A) A physician's office;
- (B) A hospital;
- (C) A health clinic;
- (D) A nonprofit health clinic, including a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic, as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(E) A free clinic as defined in § 63-6-703;

(F) A charitable organization as defined in § 48-101-501; or

(G) A nursing home as defined in § 68-11-201;

(10) "Pharmacy" means a pharmacy as defined in § 63-10-204;

(11) "Prescription drug":

(A) Has the same meaning as defined in § 63-10-204;

(B) Includes, but is not limited to, cancer drugs and anti-rejection drugs; and

(C) Does not include:

(i) Controlled substances; or

(ii) Drugs covered by the risk evaluation and mitigation strategy program of the United States food and drug administration;

(12) "Repository" means a pharmacy that:

(A) Has a license or permit in good standing with the board; and

(B) Meets the requirements established by § 63-10-503;

(13) "Supplies" means the supplies necessary to administer the prescription drugs donated pursuant to this part; and

(14) "Unopened tamper-evident packaging" has the same meaning as defined in United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements.

63-10-503. Prescription drug donation repository program.

(a) A pharmacy may elect to participate in the prescription drug donation repository program by providing written notification to the department of the following:

(1) The name, street address, and telephone number of the pharmacy and the license or registration number issued by the board;

(2) The name, telephone number, and pharmacy license number of the responsible pharmacist who is employed, or under contract, with the repository; and

(3) A statement signed and dated by the responsible pharmacist indicating that the repository meets the eligibility requirements and will comply with the program.

(b) The repository shall develop and implement standards and procedures to determine, based on basic visual inspection, that the prescription drugs appear to be unadulterated, safe, and suitable for dispensing.

(c) Donated prescription drugs must be in unopened tamper-evident packaging. However, drugs packaged in single use doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed.

(d) Donations of prescription drugs and supplies may be made on the premises of, or mailed to, a repository that participates in the program.

(e) A repository may receive, accept, replenish, repackage, and store donated prescription drugs and supplies in accordance with this part.

(f) Donation and facilitation of a donation are not considered wholesale distribution, and a person donating or facilitating a donation does not require licensure as a wholesaler.

(g) Repositories shall prioritize dispensing of donated prescription drugs and supplies as follows:

(1) First, to an indigent person;

(2) Second, to a person who has no prescription insurance or cannot afford the out-of-pocket expenses for the prescription drug or supplies prescribed; and

(3) Lastly, to another individual if an indigent, uninsured, or underinsured person is unavailable.

(h) A repository shall not charge or collect fees from an eligible individual for prescription drugs or supplies dispensed pursuant to the program. However, a repository may charge a handling fee for each donated prescription drug or supply that is dispensed.

(i) A repository may charge fees, including, but not limited to, a usual and customary charge, to donors, eligible individuals, health plans, pharmacy benefit managers, drug manufacturers, veterans' affairs hospitals, and government agencies.

(j) A repository that receives donated prescription drugs or supplies may distribute the donated prescription drugs or supplies to another repository for use pursuant to the program or to similar repository programs in other states.

(k) Participation in the program is voluntary.

63-10-504. Acceptance and dispensing of donated prescription drugs and supplies.

Prescription drugs or supplies may be accepted and dispensed under the prescription drug donation repository program in accordance with the following:

(1) Prior to the first donation from a new donor, a repository shall verify and record the following:

(A) The person or entity qualifies as a donor as defined in § 63-10-502;

(B) The donor's name, address, phone number, and license number, if applicable; and

(C) That the donor will only make donations in accordance with this part;

(2) A licensed pharmacist employed, or under contract, with the program shall inspect donated prescription drugs and supplies prior to dispensing to determine if the donated prescription drugs and supplies are suitable for dispensing pursuant to this section;

(3) Repositories shall store donated prescription drugs and supplies in a secure area in compliance with all United States food and drug administration and United States Pharmacopeia packaging and storage requirements;

(4) Donated prescription drugs and supplies must be physically or electronically separated from non-donated prescription drugs and supplies;

(5) Repositories shall redact donor information from the packaging of donated prescription drugs and supplies prior to dispensing;

(6) Donated prescription drugs and supplies may be repackaged. Repackaged donated prescription drugs must be relabeled with the drug name, dose, and expiration date;

(7) Repositories shall maintain an electronic inventory of accepted donated prescription drugs and supplies that includes the drug name, national drug code number, quantity, and date of donation;

(8) Repositories shall return or destroy donated prescription drugs or supplies that are not suitable for dispensing;

(9) Repositories shall dispose of donated prescription drugs and supplies by returning to the donor, transferring to a reverse distributor, or incinerating in an incinerator that is approved by the federal environmental protection agency;

(10) The record of transaction history for donated prescription drugs and supplies must be maintained, beginning with the donor, including all prior donations, but not including information that is not required by law to be placed on the prescription drug's label;

(11) An identifier or bar code may be used in place of information required by law for a record or label if the identifier or bar code allows for that information to be readily retrievable;

(12) Repositories shall dispense in compliance with all applicable federal and state laws and regulations for dispensing, labeling, packaging, and record keeping;

(13) An expiration date is required on all dispensed prescription drugs and supplies. If multiple packaged donated drugs are used to fill a single

prescription, then the shortest expiration date must be used for the dispensed prescription;

(14) A donated prescription drug or supply must not be dispensed after its expiration date;

(15) Donated prescription drugs must not expire before the end-use date by the patient based on the prescriber's directions;

(16) Controlled substances are not acceptable for donation and must be disposed of pursuant to regulations promulgated by the federal drug enforcement administration (DEA);

(17) Prescription drugs that are part of a risk evaluation and mitigation strategy (REMS) program of the federal food and drug administration must not be accepted for donation;

(18) Records required pursuant to this section must be retained in physical or electronic format for a period of three (3) years. A donor or repository may contract with one another or a third party to create or maintain records on each other's behalf; and

(19) Donated prescription drugs and supplies may be used to replenish inventory in compliance with applicable provisions of 42 U.S.C. § 256b and regulations promulgated pursuant to that statute.

63-10-505. Immunity and exemption.

(a) Except for acts of gross negligence, willful misconduct, or bad faith, a drug manufacturer is not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(b) Except as provided in subsection (d), a medical facility or another person who is not a drug manufacturer subject to subsection (a) is not civilly liable or subject to criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part except due to its own acts of gross negligence, willful misconduct, or bad faith.

(c) Except for acts of gross negligence, willful misconduct, or bad faith, the department of health or the board of pharmacy are not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property resulting from matters related to the donation, acceptance, distribution, or dispensing of a prescription drug donated pursuant to this part.

(d) The immunity and exemption provided in subsections (b) and (c) do not apply to the following:

(1) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(2) Acts or omissions outside the scope of the program.

63-10-506. No restriction on use of samples.

This part does not restrict the use of samples by a physician or other person legally authorized to prescribe drugs pursuant to this title during the course of the physician's or other person's duties at a medical facility or pharmacy.

63-10-507. Resale of prescription drugs not authorized.

This part does not authorize the resale of prescription drugs by any person.

63-10-508. Dispensing after expiration date prohibited.

A repository shall not dispense a prescription drug after the expiration date of the drug.

63-10-509. Donation by long-term care facility.

Notwithstanding this title, title 68, or any rule, a long-term care facility licensed under title 68 may donate prescription drugs to the repository program established by this part.

63-10-510. Authority.

The prescription drug donation repository program is governed by this part. This part supersedes a law or rule inconsistent with this part.

SECTION 2. If a provision of this act or its application to any person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are severable.

SECTION 3. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 4. This act takes effect January 1, 2024, the public welfare requiring it.